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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,235	03/17/2004	Elizabeth Dzeng	Stanford S03-060	5638
39843 7590 01/14/2009				
BELL & ASSOCIATES				
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EXAMINER				
GIBSON, ROY DEAN				
ART UNIT		PAPER NUMBER		
3739				
MAIL DATE		DELIVERY MODE		
01/14/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,235

Applicant(s)

DZENG ET AL.

Examiner

Roy D. Gibson

Art Unit

3739

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 14 and 34-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 14 and 34-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14 and 37-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear in claim 13 how the thermal exchange composition can "flow" if it is selected from a group consisting of a solid or a gel. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 14, 34-41 and 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stull (7,077,825) in view of Joye et al. (5,972,979). Stull discloses the catheter, transducer (temperature sensor # 40), marker (23) and balloon structure of claim 13 (Figure 3) except for the longitudinal disposed groove on the outer surface of the balloon and a guidewire lumen (col. 7, lines 14-50). However, Joye et al. discloses a cooling balloon catheter with a guidewire and a guidewire lumen (Figure 1, # 20) which is well known in the art (col. 3, line 50-col. 4, line 36).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Stull, as taught by Joye et al., to provide a third elongate tubular body as claimed which is a guidewire lumen.

Regarding the longitudinal disposed groove on the outer surface of the balloon, the examiner maintains that a typical heat exchange catheter balloon (flexible and pliable) can be partially inflated as required to form a groove as the balloon conforms to the shape and size of a similarly shaped anatomical structure.

Further to claims 34-36, Stull discloses the method essentially as claimed, wherein the cooling rates could obviously be determined by a skillful artisan without undue experimentation.

Further to claims 40, 41 and 45-50 the claim limitations are directed to an intended use of the device rather than to a structural modification and the Stull device would obviously be capable of providing the claimed cooling rates (col. 10, line 51-col.11, line 21).

Further to claim 43, The examiner maintains that it would have been obvious to one of ordinary skill in the art to provide a guiding catheter or sheath over at least a portion of the first elongate tubular body to assist in positioning the catheter within the patient's body, as is well known in the art.

Further to claim 44, the examiner maintains that it would have been obvious to a skillful artisan to provide a pill (digestive composition) at the end of the guide wire to assist the patient in swallowing the guidewire at the beginning of the method or procedure.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stull and Joye et al. as applied to claim 13 above, and further in view of Knowlton (6,427,089). Stull fails to disclose an ultrasound transducer affixed to the catheter. But, Knowlton discloses a stomach treatment apparatus with an ultrasound transducer used to image the device distal end (col. 13, lines 21-26). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Stull/Joye et al., as taught by Knowlton, to provide a means to image and therefore, locate and position the treatment apparatus as required by the procedure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/
Primary Examiner
Art Unit 3739

January 13, 2009